FEB - 2 2004

510(k) Summary

K033656

SUBMITTER INFORMATION:

Company Name:	Sauflon Pharmaceuticals Ltd.
Address:	49 – 53 York Street Twickenham Middlesex TW1 3LP
Phone:	020 8322 4200
Fax:	020 8891 3001
Official Correspondent	Dr Ligia Delacruz
DATE PREPARED:	14th November 2003
DEVICE NAME:	
Trade Name:	SAUFLON Flat Lens Case SAUFLON 2003 Barrel Lens Case
Common Name:	Contact Lens Case
Classification:	CLASS II (21 CFR 886.5925)

DEVICE DESCRIPTION

The SAUFLON contact lens cases are moulded plastic, flat or barrel style cases with screw top leads, similar in design to currently marketed products. The barrel style include a lens basket used for holding the lens during storage.

INTENDED USE

The SAUFLON Flat and Barrel Lens Case are intended for use for storage of soft, hard and rigid gas permeable contact lenses during chemical disinfection. Not to be used for heat disinfection.

PREDICATE DEVICE

The Bausch and Lomb Lens Case was selected as the predicate device for the SAUFLON contact lens cases.

SUMMARY OF SAFETY AND EFFECTIVENESS

Cytotoxicity, systemic toxicity and ocular irritation studies were performed to assess the safety and effectiveness of the SAUFLON Flat and Barrel Lens Case. Results of the testing show no evidence of cellular or systemic toxicity, or ocular irritation.

SUBSTANTIAL EQUIVALENCE:

The SAUFLON contact lens cases are substantially equivalent in terms of indication for use, safety and effectiveness to the Bausch and Lomb Lens Case.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

KEA Plastics Ltd.
c/o Dr. Ligia Delacruz
Sauflon Pharmaceuticals Ltd.
49-53 York Street
Twickenham, Middlesex
TW1 3LP
United Kindom

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Re: K033656
Trade/Device Name: SAUFLON Flat Lens Case
SAUFLON 2003 Barrel Lens Case
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) contact lens care products
Regulatory Class: Class II
Product Code: LRX
Dated: November 14, 2003
Received: November 21, 2003

Dear Dr. Delacruz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SAUFLON PHARMACEUTICALS LIMITED

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K033656

Device Name: SAUFLON Flat Lens Case
SAUFLON 2003 Barrel Lens Case

Indications For Use: Storage of soft (hydrophilic), hard and rigid gas permeable (RGP) contact lenses during chemical disinfection only. Not to be used for heat disinfection.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Daniel W. C. Brown, P.H.D.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K033656

Prescription Use _____ OR Over-The Counter X
(Per 21 CFR 801.109)